[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Peter Soukas, J.D., 301-594-8730; peter.soukas@nih.gov. Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Recombinant Respiratory Syncytial Virus Challenge Strain

Description of Technology:

RSV is the most important viral agent of severe respiratory tract disease worldwide, especially in infants and young children, and it also causes severe disease in the elderly and in immunocompromised individuals. There are no licensed vaccines or antivirals suitable for routine use.

This invention relates to a reverse genetics system and cDNA-derived virus for a contemporary wild-type clinical isolate of RSV of antigenic subgroup A, termed RSV strain A/Maryland/001/11, that was isolated in 2011 from an adult with respiratory illness. The genomic sequence was determined. A reverse genetics system was created encoding a recombinant, replication competent RSV that contains a codon-optimized G ORF, which was done to stabilize the cDNA for replication in bacteria. Because this virus was generated by reverse genetics, it is a "clean" virus with a well-defined passage history. Clinical study material of this challenge virus has been manufactured and is available for use as an U.S. Food and Drug Administration (FDA) regulated Investigational New Drug (IND) in clinical studies in adult volunteers within and outside of the United States. Preliminary clinical data confirmed that this virus efficiently infects and replicates in 95% of study participants pre-selected for pre-existing RSV antibody titers in the bottom 50% of the range. The challenge virus causes mild upper respiratory illness in the majority of infected participants, typical for RSV illness in otherwise healthy adults. This provides a suitable challenge system for evaluating antivirals, as well as vaccines for older children and adults. This also could be used for developing live-

attenuated RSV vaccine candidates based on this contemporary strain, using the stabilized point mutations, stabilized codon-deletions, and gene-deletions that were previously used in RSV strain A2.

This invention relates to a reverse genetics system and the encoded RSV vaccine challenge strain that infects and causes disease in RSV-experienced adults and is available for antiviral and vaccine research.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. § 209 and 37 CFR Part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Vaccine development
- Viral diagnostics
- Vaccine research

Competitive Advantages:

- Ease of manufacture
- Clinical trial material
- Low-cost vaccines
- Intranasal administration/needle-free delivery

Development Stage:

- In vivo data assessment (human)

Inventors: Ursula Buchholz (NIAID), Peter Collins (NIAID).

Intellectual Property: HHS Reference No. E-235-2018-0

Licensing Contact: Peter Soukas, J.D., 301-594-8730; peter.soukas@nih.gov.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize for development of a vaccine for respiratory or other infections. For collaboration opportunities, please contact Peter Soukas, J.D., 301-594-8730; peter.soukas@nih.gov.

Dated: October 12, 2018.

Suzanne M. Frisbie,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

[FR Doc. 2018-23311 Filed: 10/24/2018 8:45 am; Publication Date: 10/25/2018]